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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,392	08/10/2001	Jae Yong Han	DE1292	8614

7590 07/30/2003

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,392	HAN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2003 and 17 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *16-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15 and 26, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Pain only reported avian stem cells with multiple morphogenetic potentialities were derived and maintained in vitro by long-term culture of blastodermal cells. Applicants state the production of EG cells from PGCs has not previously been reported. This is not found persuasive because the cells originally isolated by Pain were from the blastoderm, including gonad cells such as PGCs and EG (embryonic germ) cells. It is not apparent why applicants believe why Pain does not culture PGCs and obtain EG cells. Pain isolated PGCs from a blastoderm and obtained cells that provided germline transmission which are EG cells. Applicants state the EG cells claimed can only be made by the methods of claims 1-15 and 26. Applicants' argument is not persuasive because the structure and function of the EG cells claimed does not differ from those known in the art. The methods of claims 1-15 and 26 do not alter the structure or function of the EG cells. Applicants argue Group III should be included because the product is not distinct from the method of using the product. Applicants argument is not persuasive because the EG cells claimed were described by Pain of record.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The effective filing date of the claimed invention is 2-11-2000, the filing date of PCT/KR00/00104, because 1999-4860, filed in Korea on 2-11-1999, did not teach isolating EG cells as claimed.

Claim Rejections - 35 USC § 112

Because the metes and bounds of the claims are unclear (see 112/2nd below), the essential culture methods required to enable one of skill to perform the method claimed cannot be determined. It is noted that, for example, Ponce De Leon (1997, Revista Brasileira de Reproducao Animal, Vol. 21, pg 96-101) taught LIF, bFGF, IGF and SCF are required for long term culture of avian PGCs. If long-term culture is required to make EG cells from PGCs, then an enablement rejection may be required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds of the starting and ending cells and the steps used to obtain them are unclear. Chang (1997, Cell Biol. International, Vol. 21, pg 495-499) and Pain (1996, Development, Vol. 122, pg 2339-2348) taught pluripotent primordial germ cells that provided chimeric chickens. It is unclear if EG cells must have a different structure or function than PGCs. The specification states EG cells are derived from PGCs (pg 1, last sentence) but does not define and distinguish EG cells and PGCs. The distinction between PGCs and EG cells as claimed cannot be determined. It is unclear if the method is directed toward culturing PGCs that become EG cells or if a population of PGCs that contain EG cells are cultured so that EG cells are preferentially obtained.

The metes and bounds of a "differentiation inhibitory factor to obtain EG cells" (claim 1) cannot be determined. It is unclear if SCF, bFGF, IL-11, or IGF-I, the factors described in the specification, are encompassed by the phrase.

Claim 1 is indefinite because the "same medium as in step (a)" is unclear. It is unclear if the phrase is limited to the medium used to culture PGCs in step (a) or merely to medium that is "supplemented with a cell growth factor and a differentiation inhibitory factor" as in step (a).

Claims 2 and 3 are indefinite because embryonic gonads are not "at a stage..." as claimed. Embryos are staged, not gonads.

The metes and bounds of "germinal ridge stroma cells" (claim 5) cannot be determined. It cannot be determined if any stromal cells from the gonad are encompassed by the phrase because such cells arise from the germinal ridge. It cannot be determined if the stromal cells must be isolated from an embryo at a particular stage. Therefore, it is unclear if the phrase limits the structure of the stromal cell or when the stromal cell is isolated.

Claim 7 is indefinite because it is unclear if the "growth factor" of claim 7 is the growth factor of claim 1 or an additional growth factor.

Claim 9 is indefinite because the metes and bounds of "units" of LIF is unclear. It cannot be determined by what standard the units are measured.

Claim 13 is indefinite because the metes and bounds of "equivalents thereof" of fibroblasts cannot be determined. Either a cell is a fibroblast, or it is not.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-15 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Pain (1996, Development, Vol. 122, pg 2339-2348)

Pain taught isolating blastodermal cells from stage IX-XI chicken embryos, culturing the cells with or without STO feeder cells, 10 ng/ ml bFGF, 20 ng/ml IGF-I, 1% SCF, 1% vol/vol LIF and 1% IL-11 (col. 2340, lines 1-12, "Preparation of culture dishes and feeder cells," Blastodermal cells," "Development of embryoid bodies in vitro"). The cells were cultured over a period of time with the same media, injected into chicken embryos and provided germline transmission (pg 2345, col. 2, last 11 lines; pg 2346, col. 2, lines 2-5). The blastodermal cells isolated by Pain were inherently PGCs because the blastoderm at stage IX-XI inherently has PGCs. The cells obtained by Pain and injected into embryos were EG cells as claimed because they provided germline transmission.

Claims 1-6, 8, 10-15 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Allioli (1994, Devel. Biol., Vol. 165, pg 30-37).

Allioli taught isolating the gonads of stage 27-28 chicken embryos and culturing the cells therein in media. The cells included PGCs and fibroblasts. The fibroblasts created a feeder layer in culture and are "germinal ridge stroma cells" as claimed because they are isolated from gonads. The PGCs of Allioli were isolated from the

germinal ridge of an avian blastoderm and were pluripotent. The media contained steel factor, LIF and FGF (pg 31, col. 2; 34, col. 2, "gonadal cell culture"; pg 36, col. 1, 2nd para.), which are cells growth factors and differentiation inhibitory factors. The phrases "to obtain EG cell colonies" (step a) and "to establish the EG cell line" are intended uses and may not occur; therefore, "culturing the EG cells..." and "recovering and subculturing the EG cells" are intended steps that may not occur. However, Allioli taught culturing the PGCs in the same medium until colonies formed (pg 34, col. 2, last full para.). The PGCs were recovered and subcultured for a period of time which is equivalent to recovering and subulturing the established cell line "in the same medium as in step a)" in step c).

Claims 1-15 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (1995, Cell Biol. Internatl. Vol. 19. No. 2, pg 143-149).

Chang taught isolating stromal cells and PGCs from the genital ridge of day 5 (stage 27-28) chicken embryos. The cells were cultured in media containing 10% FBS, 10 ng/ml of IGF, 10 ng/ml FGF and 10 units/ml LIF (pg 144, col. 1). These cells inherently contain PGCs (pg 144, col. 1 para. 4; col. 2, 3 lines from the bottom; pg 146, Fig. 2, "PGCs derived from 5-day embryonic ridge in culture"). The PGCs of Chang are isolated from the gonad of an avian blastoderm and are pluripotent. The cell culture was maintained for at least 4 days (pg 14, col. 1, 3rd para., line 5).

Chang also taught isolating PGCs from the blood of day 2 (stage 13-14) embryos and adding the day-2 PGCs to the cells isolated from the genital ridge (pg 144, col. 2, 3rd para.; col. 2, "Results"). PGCs isolated from stage 13-14 are equivalent to PGCs isolated from stage 14 as claimed because they have the same structure and function.

The phrases "to obtain EG cell colonies" (step a) and "to establish the EG cell line" are intended uses and may not occur; therefore, "culturing the EG cells..." and

"recovering and subculturing the EG cells" are intended steps that may not occur. However, Chang taught culturing the PGCs in the same medium until colonies formed (pg 145, col. 9 lines from the bottom). The PGCs were recovered and subcultured for a period of time which is equivalent to recovering and subulturing the established cell line "in the same medium as in step a)" in step c).

Claims 1-15 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (1997, Cell Biol. Internatl., Vol. 21, No. 8, pg 495-499).

Chang taught isolating germinal ridge stromal cells from day 5 (stage 27-28) embryos. The cells were cultured for 5 days in media containing IGF, FGF and LIF with germinal ridge stromal feeder cells isolated from day 5 embryos to obtain gPGCs. The gPGCs were injected into recipient embryos and provided germline transmission (pg 496, "Materials and Methods"; pg 497, Fig. 1, "Progeny of germline chimeric chickens"). The gPGCs were recovered and subcultured for a period of time which is equivalent to recovering and subulturing the established cell line "in the same medium as in step a)" in step c). The gPGCs of Chang were EG cells because they provided germline transmission, which is equivalent to establishing an "EG cell line" as claimed.

Claims 1-6, 8, 10-15 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Petitte (US Patent 6,333,192, filed 8-9-1999).

The effective filing date of the claimed invention is 2-11-2000, the filing date of PCT/KR00/00104, because 1999-4860, filed in Korea on 2-11-1999, did not teach isolating EG cells as claimed.

Petitte taught isolating PGCs and stromal cells from the gonads of stage 27-30 embryos. The cells were cultured in DMEM (col. 9, line 24-37, lines 49-55; claim 1). Petitte does not teach the avian fibroblasts were removed prior to adding the cells to STO feeder cells. Therefore, the culture of Petitte maintained for 5 days also has an avian fibroblast feeder cell matrix as claimed. The STO feeder cells can be replaced with avian fibroblast feeder cells (col. 5, line 64). LIF, IGF, FGF and SCF can be added to the media (col. 6, line 39). Thus, Petitte anticipates the claims.

Claims 1, 2, 4-15 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Petitte (US Patent 5,340,740), Petitte (US Patent 5,656,479) or Petitte (US Patent 5,840,510).

Petitte taught culturing all the cells from a stage X-XIV embryo and isolating PGCs ('740; col. 6, line 50, through col. 8, line 7; claim 1-9). The cells were seeded onto chicken embryonic fibroblast feeder layers and cultured with BRL conditioned medium (col. 7, lines 7-14, of '740; col. 6, line 44, of '479; col. 6, line 54-65, of '510). The conditioned media inherently has 0.1 to 1000 units/ml LIF as it is produced by embryonic fibroblast feed cells. The phrases "to obtain EG cell colonies" (step a) and "to establish the EG cell line" are intended uses and may not occur; therefore, "culturing the EG cells..." and "recovering and subculturing the EG cells" are intended steps that may not occur. However, Petitte taught culturing the PGCs in the same medium until colonies formed (col. 7, lines 11-13). The PGCs were recovered and subcultured for a period of time which is equivalent to recovering and subulturing the established cell line "in the same medium as in step a)" in step c).

Claims 1, 2, 4-15 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Ponce de Leon (US Patent 6,156,569).

Ponce de Leon taught isolating PGCs isolated from cells of stage XIV embryos. The cells were cultured with complete medium, LIF, FGF, IGF and SCF for at least 25 days (col. 7, line 43 through col. 8, line 53). The PGCs were pluripotent and capable of creating a chimeric chicken which is a function of EG cells. The amounts of growth factors used by Ponce de Leon were described in col. 5, lines 20-30, and col. 6, lines 3-13 are equivalent to those claimed. Thus, Ponce de Leon anticipates the claims.

Claims 1-13 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Ponce de Leon (WO 99/06534, 2-11-1999).

The effective filing date of the claimed invention is 2-11-2000, the filing date of PCT/KR00/00104, because 1999-4860, filed in Korea on 2-11-1999, did not teach obtaining EG cells from PGCs as claimed.

Ponce de Leon taught isolating PGCs isolated from cells of stage XIV embryos. The cells were cultured with complete medium, LIF, FGF, IGF and SCF (pg 27, line 25; pg 36, lines 22-25). The EG cells were produced by culturing PGCs (see title). The amounts of growth factors and STO feeder cells used by Ponce de Leon were described on pg 29, line 16, through pg 30, line 18, and are equivalent to those claimed. Thus, Ponce de Leon anticipates the claims.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER